

APR 24 1997

K970291

SECTION 17: SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92.

17.1 SUBMITTER INFORMATION

- a. Company Name: Elekta Instrument AB
- b. Company Address: St. Larsgatan 2, S-582 24
Linköping, Sweden
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Elekta Instrument AB
- e. Date Summary Prepared: January 17, 1997

17.2. DEVICE IDENTIFICATION

- a. Trade/Proprietary Name: Accessories to the Stereotactic Body Frame
- b. Classification Name: Medical charged-particle radiation therapy system

17.3 IDENTIFICATION OF PREDICATE DEVICE

<u>Company</u>	<u>Device</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
Elekta Instrument AB	Stereotactic Body Frame	K960338	April 23, 1996

17.4 DEVICE DESCRIPTION

The Stereotactic Body Frame utilizes a reference system of coordinates that can be reproducibly localized during diagnostic examination and treatment. The Accessories to

the Stereotactic Body Frame include a laser chest pointer which is mounted on an arc-ruler and is used for alignment of the patient. The coordinates used for patient positioning can be easily read on the arc-ruler holding the chest pointer and on the longitudinal ruler, along which the arc-ruler can be moved. An additional accessory to the Stereotactic Body Frame is the pillow holder, or shell. This framework is affixed to the body frame and allows for reproducible positioning of the patient within the frame. The pillow holder also allows for removal and insertion of the pillow. The pillow is available as either a vacuum bag filled with polystyrene spheres, or as a polyurethane foam-filled bag. The Stereotactic Body Frame comes equipped with a quality check instrument for verifying the accuracy of the coordinate set-up.

17.5 SUBSTANTIAL EQUIVALENCE

The Elekta Accessories to the Stereotactic Body Frame is substantially equivalent to other stereotactic frames currently in commercial distribution by Elekta Instruments AB in terms of the intended use of achieving a safe and accurate fixation and re-fixation of a patients' body for localization of targets for radiotherapy treatment.

The fundamental technical characteristics are similar to those of the predicate device and are listed on the comparison chart provided in this 510(k) submission. Differences that exist between these systems is the addition of the pillow holder which aids in the accuracy of the positioning of the patient within the frame and the conversion of the chest marker to a laser pointer. The addition of these accessories does not affect the relative safety or effectiveness of the device.

17.6 INTENDED USE

The Accessories to the Stereotactic Body Frame is a device designed for stereotactic diagnostic localization and stereotactic radiotherapy of extra cranial targets.

17.7 TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the Accessories to the Stereotactic Body Frame and the predicate device is provided in this 510(k) submission.

17.8 510(K) CHECKLIST

This notification contains all information required by 21 CFR 807.87. A completed copy of the Premarket Notification 510(k) Reviewer's Checklist is provided in this submission.